



"Efficiency has a new name"

March 9, 2012

Mr. Luis Sierra Torres, P.E.
Gerente Interno
Environmental Quality Board
P.O. Box 11488
San Juan, P.R. 00910

Re: Revision Permit PFE-27-0207-I-II-O
Revision Permit PFE-27-0404-0439-I-II-C

Dear Mr. Sierra,

On February 9 of this year, I met with Weldin Ortiz at your facilities along with Hector Agosto from Customed and Edgardo Sotto Williams who consults for Customed on environmental regulations. The purpose of this meeting was to discuss Customed's position regarding the captioned permit revisions, and try to agree on permit conditions that Customed can clearly understand and comply with.

Most of our discussions centered around our confusion regarding Condition #'s 59, 60 and 61 of the revised Operations Permit and Condition #'s 54, 55, and 56 of the revised Construction Permit. These conditions deal directly with the periodic emissions monitoring that your agency is requiring for the stack of the dry bed reactor (Safe Cell II), currently installed and operating to control potential residual emissions from the aeration room. During our discussions, Weldin supplied us with an undated memorandum written by Richard J. Kruse P.E., former head of Advanced Air Technologies, Inc., the manufacturer of the dry bed reactor emission abatement equipment we use. This memorandum outlines detailed "Monitoring Recommendations for Safe Cell II Customers". Although Hector and I did not recall seeing this memorandum before, we are familiar with the EtO monitoring system suggested by Mr. Kruse for stack monitoring since we currently use it for other purposes. After reviewing the memorandum from Mr. Kruse, which Weldin allowed us to retain for our files, we agree to use this method, following the protocol outlined in the memorandum, to perform quarterly testing of the emission stack of the dry bed reactor. We will commence this testing by the end of March 2012, and we will repeat the same testing quarterly. Attachment 1 to this letter contains the details of the Monitoring Recommendations provided by Mr. Kruse, including the recommended procedure we intend to use for this purpose.

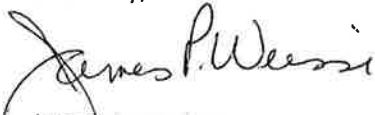
In addition, we discussed the fact that we have contracted the services of Mr. Howard Humphries from EnviroMechanics once per year when he is in Puerto Rico, to perform emissions testing according to the direct interface procedure of EPA Method 18, utilizing a gas chromatograph. Mr. Humphries completed this testing of the dry bed stack and submitted his report showing no detectable EtO emission from this source on October 17, 2011. We proposed contracting Mr. Humphries to continue to perform this

testing when he is on island, most typically during the fourth quarter of the calendar year. Therefore, Customed proposes to perform quarterly emission testing of the dry bed stack using the method suggested in the memorandum by Mr. Kruse from Advanced Air Technologies. During the quarter of the year when Mr. Humphries is on island, we will contract him to perform emission testing of the dry bed stack according to the direct interface procedure of EPA Method 18, utilizing a gas chromatograph. Should Mr. Humphries become unavailable to conduct this testing, we will coordinate with another company or consultant to perform this testing. Under this arrangement, Customed would use the stack testing method recommended by Mr. Kruse during all four quarters of the year, and use Howard Humphries for on site testing once annually. Attachment 2 to this letter contains the procedure used by Mr. Humphries during his most recent test of the dry bed stack emission, and will be the procedure followed for future annual tests.

At the close of the February 9 meeting, Weldin indicated to us that he believed that your agency would accept the emissions testing proposal that we have outlined in this letter. Please confirm to us if this belief is correct by issuing revised permits clearly stating these conditions, or providing us with some clear form of documentation containing these agreed upon conditions.

If we do not hear from you by the end of this quarter, we will continue to proceed as indicated in this letter and will look for clarification from your agency soon.

Sincerely,



James P. Weisse
General Manager



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Monitoring Recommendations Safe Cell II Customers

We are frequently asked for our recommendations for regarding monitoring efficiency of the Safe Cell II model DR-490 system. Please note the federal rules provide the authority to the local regulatory agency to accept and approve a monitoring program that meets your facility needs. Since the Safe Cell II technology falls under "other emission control devices", the monitoring plan is determined by the local agency. We offer the following suggestions.

The purpose of the monitoring request by the local regulatory agency is to verify that the system is being operated correctly and that the maintenance is being performed, all with the intent that the system continues to remove EtO as specified in your permit.

The DR-490 removes EtO at a very high efficiency initially and, as the bed capacity becomes consumed by the EtO, the efficiency gradually decreases. One of the best ways to monitor it consists of checking the outlet concentration of EtO in the exhaust at periodic intervals. We recommend that you test the outlet by inserting an EtO monitoring type badge (STEL) or similar in the outlet duct for 6 to 8 hours during a typical days run. Have the badge developed and you can then calculate the average EtO concentration in the exhaust. We have users in WA, MI, WI, NY and other states using this method – it works well. The tests are relatively inexpensive and accurate. Most of our customers use badges to schedule their reactant replacement.

Many states have approved this method of testing for our system as it encourages the owner to test the system more frequently. The badges are all OSHA approved for detecting low levels of EtO. When the EtO outlet level approaches your regulatory limit, generally 1 ppmv, you can schedule a reactant changeout. Since the efficiency decline is gradual, there is little chance that you will ever exceed your limit if you follow the above procedure. If you were to test the outlet every 6 to 9 months initially, you will soon be able to estimate the time needed to change out the reactant. After a couple of changeouts, you should adjust your test schedule to reflect that frequency.

You should also monitor the ΔP across the beds. An increase in ΔP generally indicates that the inlet air filters need attention and it does not affect the performance of the Safe Cell II for removal of EtO, however it will reduce your air flow rate.

You should be aware that the monitoring procedures for all types of systems are even now being reviewed by EPA. It is the intent of EPA to provide local agencies with discretionary authority to set monitoring procedures on a plant by plant basis, so that each company can have a realistic method that "works" with the equipment they are using.

ATTACHMENT 1

*Air Emission Permitting
Sterilization System
Customed Inc.
Fajardo Puerto Rico*

ATTACHMENT 4

**SAFE CELL II MODEL DR-490 DRY-BED REACTOR
RECOMMENDED PROCEDURE
CONTINUOUS COMPLIANCE OPERATING PARAMETER MONITORING**

SUMMARY OF RESULTS – AERATION ROOM VENT TEST

Table 1 presents the summary of results for the ARV Tests.

TABLE 1 SUMMARY OF RESULTS AAT SAFE CELL II DRY BED REACTOR CUSTOMED, FAJARDPO, PUERTO RICO TEST DATE 9/27/2011			
RUN No.	Inlet EtO Concentration (ppm)	Outlet EtO Concentration	Emissions Less Than 1.0 PPM
1	18.8	non-detect	YES
2	16.1	non-detect	YES
3	14.3	non-detect	YES

The results of the analyses are designated "non-detect" and are thus below 1.0 ppm. The lowest cylinder gas standard used to calibrate the gas chromatograph is 0.7 ppm. During each ARV test samples of inlet and outlet gases were analyzed. The concentration of inlet gases averaged 16.7 ppm over the duration of testing. A profile of the emissions over time is included in Appendix 1 chromatograms.

CHAMBER OPERATIONS FOR TESTING

The sterilization chamber was charged routine loading of product that was transferred into aeration upon completion of the sterilization cycle. The record of the sterilization cycle is included in Appendix 2 Chamber Operating Data.

PROCEDURES

The performance testing was conducted according to the direct interface procedure of EPA Method 18. No Tedlar sample bags were used. Samples were drawn through ¼ inch teflon tubing via teflon lined sample pumps. Sample was introduced to the gas chromatograph via tee-connection slip streams. Samples were drawn from the sample ports at a rate of 2 liters per minute while the slip stream into the GC was 0.1 liters per minute.